Summary Minutes of the Clean Air Scientific Advisory Committee (CASAC) and CASAC PM Review Panel Meeting
October 3, 2003, 2:00 – 5:00 PM, Ariel Rios Building, Washington D.C.

Panel Members: See Panel Roster – Attachment A.
Date and Time: Friday, October 3, 2:00 – 5:00 PM
Location: Ariel Rios Building, 1200 Pennsylvania Ave., N.W., Washington, DC.

Purpose: The purpose of this meeting was: 1) for the CASAC to review and discuss the CASAC NAAMS Subcommittee report; and 2) for the CASAC PM Review Panel to discuss follow-on matters related to its review of EPA's PM AQCD.

Attendees:

Chair:	Dr. Philip Hopke
CASAC Members:	Dr. Frederick Miller Mr. Richard Poirot Dr. Frank Speizer Dr. Sverre Vedal
Consultants:	Dr. Jane Koenig Dr. Petros Koutrakis Dr. Allan Legge Dr. Paul Lioy Dr. Morton Lippmann Dr. Joe Mauderly Dr. Gunter Oberdorster Dr. Robert Rowe Mr. Ronald White Dr. Warren White Dr. George Wolff
EPA SAB Staff:	Mr. Fred Butterfield, DFO

Others attending:

John Bachmann, EPA, OAQPS, RTP
Cristina Cann, Health Effects Institute
Jeanette Clute, Ford Motor Co.
Patricia Fitz, New York State Department of Health
Gerald Gleason, EPA, OGC
Thomas Grahame, U.S. DOE
Les Grant, EPA, NCEA, RTP
Tim Hanley, EPA, OAQPS, RTP
Denise Kennedy, Holland & Hart, LLP

John Heuss, Air Improvement Resource, Inc.
Marion Hoyer, Transportation and Air Quality
Kyle Isakower, American Petroleum Institute
Phil Johnson, Public Health and Environmental, NESCAUM
Cindy Langworthy, Hunton & Williams, LLP
Fred Lipfert, private citizen
Steve Lomax, Edison Electric
Karen Martin, EPA, OAQPS, RTP
Will Ollison, American Petroleum Institute
Ron Outen, Ron Outen Associates, LLC
Van Shrieves, EPA, NHEERL, RTP
Harvey Richmond, EPA, OAQPS, RTP
Deborah Shprentz, American Lung Association
Steve Silverman, EPA, OGC
Vanessa Vu, EPA, SAB
Jane Warren, Health Effects Institute
Gerald Yamata, O'Connor and Hannan

Meeting Summary

The discussion generally followed the issues and general timing as presented in the teleconference Agenda (Attachment B). The meeting began at 2:00 P.M. and lasted until 4:45 P.M. on Friday, October 3, 2003.

Convene Teleconference, Attendance, and Introduction

Mr. Fred Butterfield, Designated Federal Officer (DFO) for the CASAC, convened the teleconference, welcomed participants, and briefly reviewed the call agenda. He added that the teleconference is held pursuant to the Federal Advisory Committee Act (FACA) requirements as outlined in 41 CFR Parts 101-6 and 102-3, including the requirement for public notice and an open meeting. Minutes were taken and will be available after being certified, although no transcript was recorded.

All members of the CASAC and the particulate matter (PM) review panel have submitted confidential financial disclosure forms, which were reviewed and approved by the SAB's ethics and FACA officials.

Purpose of Meeting

Dr. Phil Hopke, CASAC Chair, explained that the purpose of the first part of the call would be for the CASAC to review and approve the report prepared by the National Air Quality Monitoring Standards (NAAMS) subcommittee. The report was initially reviewed in early July 2003, and the comments and recommendations were given on the

document. The CASAC NAAMS subcommittee was constituted at that time to review the Agency report on monitoring needs, drafted about one year ago. The purpose of today's meeting was for the entire CASAC to review the report of the subcommittee.

Part 1: CASAC Review of and Deliberation on the CASAC NAAMS Subcommittee Report

Mr. Butterfield opened the discussion to comments from members of the public who may not have sent comments in advance; no public comments were given. He then explained that the teleconference was structured to comply with a FACA requirement stating that advice from a subcommittee must be transmitted to the Agency via the parent committee – in this case, the full CASAC. Members of the subcommittee were permitted to provide comments during the call only after being recognized by the Chair, Dr. Fred Miller.

Dr. Speizer asked whether the CASAC would need to review and sign off on the document a second time, after the comments from today's meeting were incorporated. Dr. Hopke explained that it would not be necessary for the CASAC to review the revised draft; however, the NAAMS Subcommittee (or its successor CASAC subcommittee) did see a need for follow up review as the strategy is being implemented.

Mr. Butterfield added that the Agency has the option of asking the CASAC for a review of the final document, though this is not its current plan.

Dr. Vedal began with his comments on the report and brought up the issue of the inherent conflict in a monitoring network related to the objectives for such a network. Specifically, the document is not clear on how these objectives would be prioritized, a topic central to the design of a monitoring network.

Dr. Miller agreed with Dr. Vedal and commented that the panel should word strongly its suggestion of explaining the reasoning behind the prioritization of objectives. He added that the executive summary (p. 19) should go into more detail on the topic of the level of equity among the states.

The committee also discussed the issue of prioritizing its own recommendations, or at least summarizing them all at the end of the executive summary, as opposed to having them interspersed throughout the text. Most panel members agreed with this approach.

Dr. Speizer suggested proposing some way for the panel to oversee the implementation of its recommendations, without overstepping its role.

Dr. Miller explained that, although the panel cannot do the Agency's job by prioritizing its objectives, a recommendation has already been made to form a committee that will serve as an ongoing review board and oversee the progress of implementation. The recommendation to form this standing subcommittee can be found on page 9 of the draft NAAMS Subcommittee report.

Dr. Hopke added that the NAAMS report subcommittee was created to fulfill a specific task. Until such time as the Agency decides to form a permanent monitoring committee, there is no appropriate body to report back to, apart from the full CASAC. He suggested that Dr. Vanessa Vu inform the Administrator's office of the opinion of the NAAMS subcommittee on creating this additional committee within CASAC.

Mr. Butterfield suggested that the new committee could be formed by renaming the current NAAMS subcommittee, which would become a CASAC subcommittee on air quality monitoring. He confirmed that, until this is done, the full CASAC should be the recipient of any report back on implementation.

Dr. Vu confirmed that it is certainly acceptable for the CASAC to recommend creation of the committee, and added that the SAB staff office would be responsible for the allocation of sufficient resources if/when the new subcommittee is formed.

Dr. Hopke suggested moving on to other topics in the report. He brought up an apparent inconsistency regarding L-1 sites. Specifically, he thought the subcommittee report stresses the need for such sites, it does not acknowledge how this will be achieved, given the fact that there are currently insufficient resources for new sites.

Dr. Miller agreed that a statement could be added to the report stating that the committee sees this as a priority worth the effort of obtaining additional resources. Other panel members concurred.

Mr. Poirot commented that, in the past, it has been possible to fund such efforts by taking care to avoid redundancy and inefficiency. Over the course of discussion and evolution of this strategy, however, it has become clear that a substantial new air toxics program must be initiated.

Dr. Miller remarked that there is also the potential for a "disconnect" by not including any aspects of risk assessment analysis. He disagreed with a statement in the document which claims all risk from air toxics can be attributed to mobile sources, and cited examples of non-mobile sources that could contribute to risk.

Some panel members agreed with this, while others explained that the sheer amount of mobile sources such as automobiles lends some credence to the fact that they account for the majority of risk.

Dr. Miller added a final point concerning the increased need for monitoring in rural areas, adding that tribal areas have been largely ignored. He also stated that the capitalization of the phrase "Indian Country" (found on p. 41 of the NAAMS Summary Document) can be considered offensive and should be modified.

Dr. Miller then concluded the discussion by summarizing the major recommendations discussed:

- Include a summary of the panel's recommendations at the end of the Executive Summary;
- Stress the importance of L-1 sites, while making sure funding is not removed from other important areas to fund such sites; and
- Expand the discussion on page 8 on the importance of air toxics.

In response to Dr. Hopke, Dr. Miller confirmed that the subcommittee would not need to see the report again, but can consider it final once the recommendations from today's discussion have been included.

The subcommittee approved the report to be finalized with the changes discussed today.

Dr. Vu suggested that the recommendations of the subcommittee, summarized in the last paragraph of the Executive Summary, should be worded as recommendations of the entire CASAC.

Dr. Miller agreed to re-word the paragraph in question accordingly.

Mr. Butterfield thanked the NAAMS subcommittee and the CASAC for their deliberations and their work on the report. He concluded this portion of the conference call and asked participants to move on to Part 2.

Part 2: CASAC PM Review Panel (PMRP) Discussion of Follow-On Matters Related to its Review of EPA's PM AQCD

Dr. Les Grant (EPA/ORD/NCEA) briefly described the events which led to the restructuring of PM AQCD Chapter 9, "Integrative Synthesis." Recommendations for the restructuring of this chapter were the major outcome from a meeting of the CASAC which took place in August 2003. Dr. Grant's team has worked since that meeting to develop an approach for restructuring. The 1996 PM Criteria Document (Chapter 13) was used as a good example of an effort at bringing together information.

The team decided to identify several key issues and then pose a set of questions to focus on, centering on the new information that has been published and its implications for changes to any key conclusions drawn in the 1996 document. This led to the outline prepared and provided to the panel as part of the meeting materials (see Attachment E). The basic approach was to pose a question in relation to a key topic or conclusion from the prior integrated synthesis; provide a snapshot of what was previously said; then present any new information from studies conducted since, and how it might be used to arrive at new conclusions.

Dr. Grant noted that the committee's feedback would be particularly helpful in the area of welfare effects, particularly on the topics of vegetation and ecosystems, as no information on these topics was included in the 1996 document.

Dr. Hopke suggested that the panel begin its discussion by focusing on general questions on the framework, and proceed to comments on the details as time permits. He then summarized comments submitted by Dr. McClellan (Attachment F), who expressed the view that the framework should be restructured to focus more directly on the four elements of a standard (i.e., indicator, averaging time, level, and form). While some members agreed that these objections have merit, the committee did not support such restructuring of the framework. Rather, the discussion turned to ways in which these issues could be addressed within the context of the draft framework. One approach suggested was to add some questions that specifically address the issues raised.

Dr. Miller agreed that Dr. McClellan's concerns should be addressed, but was of the opinion that this can be done within the context of the current outline, specifically by expanding the introduction to include them. Some members stressed that policy decisions should be addressed not in the criteria document, but rather through the staff paper. Some members also noted that it is a policy decision to determine standards that provide an adequate margin of safety for public health protection, though decisions on the elements of such standards are informed by the scientific information available. The committee concluded this general discussion by agreeing that the framework did not need to be restructured, noting that it is possible to provide, within the proposed outline, the information needed to inform such decisions.

The discussion moved to other topics, and a panel member recommended that the chapter be shortened to the major points; it is not necessary to have sections "A" and "B" for each of these points.

Dr. Koenig agreed with this suggestion, stating that the document would be easier to read if the important points can be expressed succinctly. She added that a reiteration of the 1996 data is not necessary; these data can instead be cited, and those interested can look up the relevant publications.

Dr. Grant explained that it is not his team's intent to reiterate the findings of the 1996 document. Rather, the key conclusions will be summarized, as a lead-in to discussion on important new information. In response to another panel member he added that several areas not represented in 1996 – such as cardiac effects – would be included in the new document.

Dr. Lioy cautioned against assuming that the conclusions reached in 1996 still hold, as there was some controversy over some of those findings, and some new uncertainties have been discovered.

Dr. Grant agreed that the group will need to be cautious in how previous conclusions are characterized, adding that any new uncertainties will also be addressed and explained.

Dr. Mauderly remarked that it is important nevertheless to portray how knowledge has changed since the last document. He explained his reasoning by stating that this is a review document; reviews are mandated at certain time intervals, and part of their purpose is to determine whether the Agency's views on standards should change based on information obtained since the last review. It makes sense for emphasis to be placed on what was learned in the interval between two such documents. He acknowledged that this can be accomplished in several different ways to suit a document's organization.

Dr. Hopke reiterated the questions, which examine whether the five topic areas cover the key ingredients; whether there is an overarching issue that may have been missed; and whether the framework indeed covers the health effects problems.

Mr. White commented that, in his opinion, the questions were comprehensive. Dr. Vedal agreed with Mr. White.

A panel member brought up the issue of fine versus coarse particles and commented that there are other aspects of size distribution worth emphasizing apart from the fine/coarse distinction. He offered the example of super coarse particles, and effects seen from such particles following the events at the World Trade Center.

Dr. Miller stated that he would endorse the idea of taking particle distribution to a more general level, but added that the exposures to super-coarse particles seen at the World Trade Center were much above what has been seen in ambient measurements.

Dr. Lippmann agreed that the World Trade Center was a special case beyond the scope of this document. He recommended that particles be defined in the document using international definitions, rather than the descriptions used by EPA.

Dr. Miller argued that the document does define the terms the authors chose to use, adding that this may not be the appropriate place to encourage EPA to join in using international standard terms.

Dr. Miller than moved to another topic, and stated that there is a lot of new dosimetry information that was not available in 1996, and could be added to section 9.2.4.

Dr. Grant explained that the new dosimetry data would be included.

Mr. White suggested adding a bullet on studies that link epidemiology and human clinical exposure, such as the Utah Valley study.

Dr. Grant explained that this would be added to the document and discussed.

Dr. Hopke reminded the panel members that there would be no committee report arising out of this discussion, as it is a consultation rather than a review. He asked committee members to provide their comments as soon as possible, and preferably by the weekend

(October 4-5), so that Dr. Grant's team has time to incorporate them prior to the next meeting, scheduled for November 12, 2003.

Dr. Vedal listed several suggestions for the writing team, including considering chronic, as well as acute effects in section 9.2.2; comparing risk among subgroups wherever possible in section 9.2.4; and providing some information on how the studies used for impact assessment were chosen among the many that are available.

Dr. Grant agreed with these suggestions, but stated that there is only limited information available for making direct comparisons among subgroups.

Dr. Hopke suggested the committee move on to discussion of welfare effects. He stated that he received comments from Dr. Taylor that indicated he did not see these effects addressed, but added he would follow up with Dr. Taylor to clarify since these effects were included in the framework.

Dr. Legge wanted to know how the issue of the cumulative nature of ecosystem responses would be covered in the document. He also commented that, though mixtures and multiple stressors have distinct roles in causing health effects, there is a lack of adequate monitoring in these areas.

Dr. Grant explained that cumulative effects might be addressed by emphasizing the importance of long term depositions (such as nitrogen or phosphorus), as well as other such key issues. He added that mixtures and multiple stressors would be highlighted as one of the important areas of uncertainty.

Dr. Rowe commented that the revised welfare effects section should be more concise, and more in line with regulatory criteria, though he acknowledge the latter may be difficult to accomplish. He also noted that some visibility-related reports included in the Staff Paper are not referenced in the Criteria Document and such references should be added to Chapter 4 of that document.

Dr. Grant agreed with the need for the section to be concise, and added that the writing team would make sure to include reference to the relevant reports in Chapter 4 of the Criteria Document.

Dr. Hopke then solicited any final comments on welfare effects; no comments were offered, and the writing team had no questions to ask the committee.

Dr. Grant stated that the discussion has been helpful, adding that the writing team will be able to accommodate many of the comments and concerns expressed by committee members. He reiterated the committee's conclusion that the general framework for Chapter 9 will remain as proposed, including noting the key conclusions from the 1996 document, followed by discussion on how the integration of the newly available information alters or adds to the key conclusions from the last review.

In response to Mr. Butterfield's question, Dr. Grant then outlined the team's planned schedule until the next committee meeting on November 12. He projected that the majority of the chapter revisions would be completed about two weeks in advance of the November 12 meeting.

Some committee members expressed concern that this schedule may be adequate for the committee, but would provide little time for soliciting public comments.

Dr. Grant stated that the team would try to allow some time for public comments, but the time available would likely be less than thirty days.

Mr. Butterfield explained that there will be opportunity to present public comments during the November 12 meeting, and added that he would address the short comment period in the *Federal Register* notice of the meeting. In response to questions from the committee, he added that there is no mandated minimum time for accepting public comments on a document.

Dr. Hopke stated that the committee has an obligation to attempt to finish this document in the time specified, but added that it would be incumbent on EPA to request more time if it becomes clear that this is not possible. He explained that none of the parties would accept an inappropriate document which does not meet the statutory requirements.

Mr. Butterfield then asked Mr. Fred Lipfert to reiterate the comments he had provided in writing to the committee (Attachment H), as he was present on the teleconference.

Mr. Lipfert asked whether EPA would incorporate the results of the Veterans study, and from other long-term studies, in the criteria document.

Dr. Grant confirmed that these studies would be reviewed and incorporated if the writing team determines that they would add new information.

In response to a final question by a committee member, Mr. Butterfield confirmed that the outline of Chapter 9 is available on the SAB website, adding that he could email the URL [Web address] to those who request it.

Meeting Conclusion

At the conclusion of the discussion, the Chair thanked the committee members and all call participants. Dr. Grant also thanked the committee for its helpful comments. The DFO adjourned the meeting at 4:45 P.M.

Action Items:

- Submit comments on PM AQCD Chapter 9 (Integrative Synthesis) to Phil Hopke or to Fred Butterfield as soon as possible, but preferably by the weekend of October 4-5.
- Fred Butterfield will re-send Roger McClellan's comments to all committee members, as some did not receive them.

Respectfully Submitted: Certified as True:

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ATTACHMENTS

Attachment A:	Roster of the CASAC and Particulate Matter Review Panel
Attachment B:	Teleconference Agenda
Attachment C:	Federal Register Notice
Attachment D:	Participant Sign-In Sheet
Attachment E:	Outline of Chapter 9: Integrative Synthesis
Attachment F:	Roger O. McClellan Written Comments
Attachment G:	Morton Lippmann Written Comments
Attachment H:	Fred Lipfert Written Comments
Attachment I:	George T. Wolff Written Comments

ATTACHMENT A

U.S. Environmental Protection Agency
Science Advisory Board
Clean Air Scientific Advisory Committee
CASAC Particulate Matter Review Panel*

CHAIR

Dr. Philip Hopke, Bayard D. Clarkson Distinguished Professor, Department of Chemical Engineering, Clarkson University, Potsdam, NY

Also Member: Research Strategies Advisory Committee
Executive Committee

CASAC MEMBERS

Dr. Frederick J. Miller, Vice President for Research, CIIT Centers for Health Research, Research Triangle Park, NC

Mr. Richard L. Poirot, Environmental Analyst, Air Pollution Control Division, Department of Environmental Conservation, Vermont Agency of Natural Resources, Waterbury, VT

Dr. Frank Speizer, Edward Kass Professor of Medicine, Channing Laboratory, Harvard Medical School, Boston, MA

Dr. George E. Taylor, Professor and Assistant Dean, School of Computational Sciences, George Mason University, Fairfax, VA

Dr. Sverre Vedal, Professor of Medicine, National Jewish Medical and Research Center, Denver, CO,

Dr. Barbara Zielinska, Research Professor, Division of Atmospheric Science, Desert Research Institute, Reno, NV

CONSULTANTS

Dr. Jane Q. Koenig, Professor, Department of Environmental Health, School of Puublic Health and Community Medicine, University of Washington, Seattle, WA

Dr. Petros Koutrakis, Professor of Environmental Science, Environmental Health , School of Public Health, Harvard University (HSPH), Boston, MA

Dr. Allan Legge, President, Biosphere Solutions, Calgary, Alberta

Dr. Paul J. Lioy, Associate Director and Professor, Environmental and Occupational Health Sciences Institute, UMDNJ - Robert Wood Johnson Medical School, NJ

Dr. Morton Lippmann, Professor, Nelson Institute of Environmental Medicine, New York University School of Medicine, Tuxedo, NY

Dr. Joe Mauderly, Vice President, Senior Scientist, and Director, National Environmental Respiratory Center, Lovelace Respiratory Research Institute, Albuquerque, NM

Dr. Roger O. McClellan, Consultant, Albuquerque, NM

Dr. Gunter Oberdorster, Professor of Toxicology, Department of Environmental Medicine, School of Medicine and Dentistry, University of Rochester, Rochester, NY

Dr. Robert D. Rowe, President, Stratus Consulting, Inc., Boulder, CO

Dr. Jonathan M. Samet, Professor and Chair, Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

Mr. Ronald White, Research Scientist, Epidemiology, Bloomburg School of Public Health, Johns Hopkins University, Baltimore, MD

Dr. Warren H. White, Visiting Professor, Crocker Nuclear Laboratory, University of California - Davis, Davis, CA

Dr. George T. Wolff, Principal Scientist, General Motors Corporation, Detroit, MI

SCIENCE ADVISORY BOARD STAFF

Mr. Fred Butterfield, CASAC Designated Federal Officer, 1200 Pennsylvania Avenue, NW, Washington, DC, 20460, Phone: 202-564-4561, Fax: 202-501-0582, (butterfield.fred@epa.gov) (FedEx: Fred A. Butterfield, III, EPA Science Advisory Board (1400A), Ariel Rios Federal Building North, Suite 6450, 1200 Pennsylvania Ave., NW, Washington, DC, 20004, Tel.: 202-564-4561)

* Members of this SAB Panel consist of:

a. SAB Members: Experts appointed by the Administrator to serve on one of the SAB Standing Committees;

b. SAB Consultants: Experts appointed by the SAB Staff Director to a one-year term to serve on ad hoc Panels formed to address a particular issue;

c. Liaisons: Members of other Federal Advisory Committees who are not Members or Consultants of the Board;

d. Federal Experts: "Federal Experts" are federal employees who have technical knowledge and expertise relevant to the subject matter under review or study by a particular panel.

ATTACHMENT B

U.S. Environmental Protection Agency
Clean Air Scientific Advisory Committee (CASAC) and
CASAC Particulate Matter (PM) Review Panel

Friday, October 3, 2003 – Public Teleconference Meeting
2:00 to 5:00 pm Eastern Time
Ariel Rios Federal Building North – Conference Room 6013
1200 Pennsylvania Avenue, NW, Washington, DC 20460

Teleconference Meeting for: (1) CASAC Review of and Deliberation on the Report of the CASAC National Ambient Air Monitoring Strategy (NAAMS) Subcommittee; and (2) CASAC PM Review Panel Discussion of Follow-On Matters Related to its Review of EPA's Air Quality Criteria Document (AQCD) for Particulate Matter (Fourth External Review Draft)

Final Meeting Agenda

Friday, October 3, 2003

2:00 pm	**Convene Teleconference; Call Attendance Introductions and Administration**	Mr. Fred Butterfield, CASAC DFO
2:10 pm	**Purpose of Meeting**	Dr. Phil Hopke, Chair

Part 1: CASAC Review of and Deliberation on the CASAC NAAMS Subcommittee Report

2:15 pm	**Overview and Summary of NAAMS Subcommittee Report**	Dr. Hopke
2:25 pm	**Public Comment Period**	Mr. Butterfield (Facilitator)
2:35 pm	**CASAC Members' Discussion and Deliberation**	CASAC Members*
2:55 pm	**Summary and Next Steps**	Dr. Fred Miller and Mr. Butterfield

*This portion of the teleconference will be chaired by Dr. Fred Miller, and those CASAC Members who are also NAAMS Subcommittee Members (including Dr. Hopke) will recuse themselves from the deliberations concerning the NAAMS report.

Friday, October 3, 2003

Part 2: CASAC PM Review Panel (PMRP) Discussion of Follow-On Matters Related to its Review of EPA's PM AQCD

3:00 pm	**Presentation on Framework Questions leading to restructuring of PM AQCD Chapter 9, "Integrative Synthesis"**	Dr. Les Grant, Director, National Center for Environmental Assessment (NCEA-RTP)
3:15 pm	**CASAC PM Review Panelists' Discussion**	CASAC PMRP Members & Consultants
4:30 pm	**Public Comment Period**	Mr. Butterfield (Facilitator)
4:50 pm	**Summary and Next Steps**	Dr. Hopke
5:00 pm	**Adjourn Meeting**	Mr. Butterfield

business information. EPA reserves the right to make final confidentially decisions in accordance with Agency regulations at 40 CFR part 2, subpart B. If no such claim accompanies the proposal when it is received by EPA, it may be made available to the public by EPA without further notice to the applicant.

X. Congressional Review Act

Under the Agency's current interpretation of the definition of a ''rule,'' grant solicitations such as this which are competitively awarded on the basis of selection criteria, are considered rules for the purpose of the Congressional Review Act (CRA). The CRA, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), generally provides that before a rule may take effect, the agency promulgating the rules must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements, Risk reduction.

Dated: August 25, 2003.

Thomas C. Voltaggio,

Acting Regional Administrator, Region III.

[FR Doc. 03–23275 Filed 9–11–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7557–6]

Science Advisory Board Staff Office; Clean Air Scientific Advisory Committee; Notification of Public Advisory Committee Meeting (Teleconference)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency), Science Advisory Board (SAB) Staff Office announces a publicly-accessible teleconference: for the Clean Air Scientific Advisory Committee (CASAC) to review, deliberate on, and approve the report of the CASAC National Ambient Air Monitoring Strategy (NAAMS) Subcommittee; and for the CASAC Particulate Matter (PM) Review Panel to discuss follow-on matters related to its review of the EPA Air Quality Criteria Document for Particulate Matter (Fourth External Review Draft).

DATES: The teleconference will take place on Friday, October 3, 2003, from 2 to 5 pm (Eastern Time). The CASAC will discuss the report of the CASAC NAAMS Subcommittee from 2 to 3 pm; and the CASAC PM Review Panel will discuss follow-on matters related to the draft PM Air Quality Criteria Document from 3 to 5 pm.

FOR FURTHER INFORMATION CONTACT: Members of the public who wish to obtain the teleconference call-in numbers and access codes should contact Ms. Delores Darden, EPA Science Advisory Board Staff, at telephone/voice mail: (202) 564–2282, or e-mail: *darden.delores@epa.gov,* or Ms. Sandra Friedman, EPA Science Advisory Board Staff, at telephone/voice mail: (202) 564–2526, or e-mail: *friedman.sandra@epa.gov.*

Any member of the public who wants further information concerning this teleconference, or who wishes to submit written or brief oral comments (five minutes or less), must contact Mr. Fred Butterfield, Designated Federal Officer (DFO), EPA Science Advisory Board (1400A), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone/voice mail: (202) 564–4561; fax: (202) 501–0582; or e-mail: *butterfield.fred@epa.gov.* Requests to provide oral comments must be in *writing* (e-mail, fax or mail) and received by Mr. Butterfield no later than noon Eastern Time five business days prior to the teleconference in order to reserve time on the meeting agenda. Written comments (preferably via e-mail) should be sent to Mr. Butterfield by the same deadline so that these comments can be provided to the CASAC or the CASAC PM Review Panel, as applicable, prior to the teleconference. See additional instructions in the section below entitled, ''Providing Oral or Written Comments at SAB Meetings.'' General information concerning the CASAC or the EPA Science Advisory Board can be found on the EPA Web site at: *http://www.epa.gov/sab.*

SUPPLEMENTARY INFORMATION: *Summary:* The Clean Air Scientific Advisory Committee, which comprises seven members appointed by the EPA Administrator, was established under section 109(d)(2) of the Clean Air Act (42 U.S.C. 7409) as an independent scientific advisory committee, in part to provide advice, information and recommendations on the scientific and technical aspects of issues related to air quality criteria and national ambient air quality standards (NAAQS) under sections 108 and 109 of the Act. The CASAC, which is administratively located under the EPA Science Advisory Board Staff Office, is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. The CASAC and CASAC Particulate Matter Review Panel will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Background: The CASAC NAAMS Subcommittee is charged with providing advice, information and recommendations to the Agency on the technical bases and design aspects of the National Ambient Air Monitoring Strategy. The NAAMS Subcommittee held a public meeting in Research Triangle Park, North Carolina, on July 8–9, 2003 (68 FR 34945, June 11, 2003) to review the NAAMS document. The Subcommittee will report to the Administrator of EPA through the CASAC.

The CASAC PM Review Panel is charged in part with providing advice, information and recommendations on the scientific and technical aspects of issues related to air quality criteria and NAAQS for particulate matter, under sections 108 and 109 of the Clean Air Act. The PM Review Panel reports directly to the Administrator of EPA. This teleconference is a follow-on to the Panel's review of the EPA Air Quality Criteria Document for Particulate Matter (Fourth External Review Draft), which review took place in a public meeting held in Research Triangle Park on August 25–26, 2003 (68 FR 47060, August 7, 2003), and specifically to discuss the restructuring of Chapter 9 (Integrative Synthesis) of that document.

Availability of Additional Meeting Materials: The draft agenda for the CASAC and CASAC PM Review Panel teleconference will be posted on the SAB Web site at: *http://www.epa.gov/sab* (under the ''Agendas'' subheading) in advance of the meeting. The draft report of the CASAC NAAMS Subcommittee, and any other materials that may be available, will also be posted on the SAB Web site during this time-frame.

Providing Oral or Written Comments at SAB Meetings: It is the policy of the

EPA Science Advisory Board Staff Office to accept written public comments of any length, and to accommodate oral public comments whenever possible. The EPA Science Advisory Board Staff Office expects that public statements presented at its meetings will not be repetitive of previously-submitted oral or written statements. *Oral Comments:* In general, for teleconference meetings, opportunities for oral comment will usually be limited to no more than three minutes per speaker and no more than fifteen minutes total for all speakers. The deadline for getting on the public speaker list for this teleconference is given above. Speakers who attend the teleconference in person should bring at least 35 copies of their comments and presentation slides for distribution to the reviewers and public at the meeting. *Written Comments:* Although the SAB Staff Office will accept written comments until the date of the teleconference (unless otherwise stated), written comments should be received in the SAB Staff Office at least one week prior to the meeting date so that the comments may be made available to the committee for their consideration. Comments should be supplied to the DFO at the address/contact information noted above in the following formats: one hard copy with original signature, and one electronic copy via e-mail (acceptable file format: Adobe Acrobat, WordPerfect, Word, or Rich Text files in IBM–PC/Windows 95/98 format). Those providing written comments and who attend the teleconference in person are also asked to bring 35 copies of their comments for public distribution.

Meeting Access. Individuals requiring special accommodation to access this teleconference, or who wish to attend this teleconference in person, should contact Mr. Butterfield at the telephone or e-mail address provided above at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: September 8, 2003.

Vanessa T. Vu,

Director, EPA Science Advisory Board Staff Office.

[FR Doc. 03–23274 Filed 9–11–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7557–8]

Science Advisory Board Staff Office; Ecological Processes and Effects Committee; Notification of Public Advisory Committee Meeting; Consultation on EPA's Strategy on Suspended and Bedded Sediments; Discussion of EPEC Activities in Fiscal Year 2004

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA), Science Advisory Board Staff Office (SAB), Ecological Processes and Effects Committee (EPEC) will hold a face-to-face meeting to conduct a consultation on EPA's strategy for developing water-quality criteria for suspended and bedded sediments. In addition, EPEC members will discuss EPEC activities for fiscal year 2004.

DATES: The meeting will begin on Thursday, October 2, 3003, at 8:30 am (Eastern Time) and adjourn no later than 5:30 pm that day.

ADDRESSES: The meeting will be held in Washington, DC. Location of the meeting will be announced on the SAB Web site, *http://www.epa/sab.* For further information concerning the meeting, please contact Dr. L. Joseph Bachman (see contact information below).

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information concerning this meeting must contact Dr. L. Joseph Bachman, Designated Federal Officer, USEPA Science Advisory Board Staff Office, (1400A), 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone/voice mail at (202) 564–3968; fax at (202) 501–0582; or via e-mail at *bachman.joseph@epa.gov.*

SUPPLEMENTARY INFORMATION: *Action:* Pursuant to the Federal Advisory Committee Act, Public Law 92–463, notice is hereby given that the Ecological Processes and Effects Committee (EPEC) of the U.S. EPA Science Advisory Board (SAB) will meet on Thursday October 2, to hold a consultation on EPA's strategy for developing water-quality criteria for suspended and bedded sediments. In addition, EPEC members will discuss possible EPEC activities for fiscal year 2004. The meeting is open to the public; however, seating is limited and available on a first come basis.

Availability of the Meeting Materials: Any meeting materials will be made available from the EPA's Office of Water (OW) and the Office of Research Development (ORD). The proposed agenda for the meeting will be posted approximately 10 calendar days prior to the meeting at the SAB's Web site at *http://www.epa.gov/sab/panels/epecsabspanel.htm.* Links to available meeting materials will also be posted at this location. For questions and information concerning the agenda, please contact Dr. L. Joseph Bachman (see contact information above).

Background for Consultation on Suspended and Bedded Sediments

The Ecological Processes and Effects Committee (EPEC) of the EPA Science Advisory Board was asked by the Health and Ecological Criteria Division of the Office of Science and Technology, Office of Water, to provide a consultation on potential approaches on a strategy for developing water-quality criteria for Suspended and Bedded Sediments (SABS). A request for nominations for consultant panel members to provide additional expertise to EPEC appeared in the **Federal Register** on July 30, 2003 (68 FR 44758–44760). That request contained a more detailed description of the regulatory context of the SABS issue and the scientific approaches being considered in the strategy development.

In 1976, EPA issued a water quality criteria recommendation under the Clean Water Act for solids and turbidity. For a variety of reasons, the States seldom use this criterion. It is questionable whether this criterion would achieve intended protection for all different designated uses for water bodies. SABS occurs naturally in streams in a wide range of concentrations—levels that might be perfectly normal in one water body could be indicative of impairment in another.

Although most States currently have water quality criteria that can be applied to manage SABS, these are typically based on turbidity, suspended solids or settleable solids, and their effectiveness for dealing with all water quality impairments caused by SABS, especially as benchmarks for aquatic life protection based on natural levels, is questionable. In recent consultations with State representatives, the need for new water quality criteria for SABS or methodologies for deriving them on a site-specific basis was identified as one of the highest priorities for the water quality criteria program. As a result, the EPA Office of Water has concluded that to better manage SABS in all types of water bodies and for all designated uses, State and Tribal water quality managers

CASAC TELECONFERENCE ~ OCTOBER 3, 2003

On-Line T	Name	Company	Telephone#	Comment
	1. Bryan Baldwin	Manager, Environmental Assessment Department	202-257-6333	
	2. Bob Bessette	Council of Industrial Boiler Owner (CIBO)	703-250-9042	
T	3. ~~Kurt Blase~~ Gerald Yamata	O'Connor & Hannan	202-887-1411	
	4. Susan Collet			
T	5. Jeanette Clute	Ford Motor Co.		
	6. Libby Faulk	U.S. EPA- Air & Radiation Program Denver, Colorado	303-312-6083	
	7. Joyce Fisher			
T	8. Patricia Fritz	New York State Dept. Of Health	518-402-7820	
	9. Adam Gitlin	Environmental Defense	212-616-1233	
T	10. Thomas Grahame	US Dept of Energy	202-586-7149	
	11. Richard Guillot	Environmental Engineer EPA Region 4	404-562-9050	
T	12. Denise Kennedy	Holland & Hart LLP	303-295-8489	
	13. Lisa Herchberger	Research Scientist Environmental Outcome Division	651-296-7874	
T	14. John Heuss		586-786-0827	
T	15. Marion Hoyer	Environmental Scientist Transportation & Air Quality	734-214-4513	
T	16. Kyle Isakower	American Petroleum Insitute	202-682-8314	
T	17. Phil Johnson	Public Health & Environmental, NESCAUM	617-367-8540	
	18. Carole Kammel		703-838-1879	

CASAC TELECONFERENCE ~ OCTOBER 3, 2003				
T	19. Cindy Langworthy	Hunton &Williams LLP	202-828-3783	
	20. Jeffrey Marks	Director Air Quality Resources and Environmental Policy	202-637-3176	
	21. Dave Mcneill	Air Program Manager Utah Division of Air Quality	801-536-4037	
	22. Lucas Neas		919-966-9961	
T	23. Ron Outen	Ron Outen Associates LLC	301-530-0054	
	24. Michael Reale			
T	25. Deborah Shprentz	Consultant to the American Lung Association (ALA)	703-437-0959	
	26. Linda Tombras Smith	Manager, Health and Ecosystems Assessment Section California Environmental Protection Agency		
	27. Joe Suchecke		312-827-8734	
T	28. Jane Warren	Health Effects Institute (HEI)	617-886-9330 Ext. 301	
T	29. Cristina Cann	HEI	617-886-9330 Ext. 344	
	30. Bob Yuhnke			
T	31. Will Ollison	American Petroleum Institute (API)		
T	32. Steve Lomax	Edison Electric	202-508-5710	
T	33. Fred Lipfert	private citizen	631-261-5735	
T	34. Tim Hanley	EPA-OAQPS-RTP		
T	35. Van Reves	EPA-NHEERL-RTP		
T	36. Harvey Richmond	EPA-OAQPS-RTP		
T	37. Karen Martin	EPA-OAQPS-RTP		

CASAC TELECONFERENCE ~ OCTOBER 3, 2003				
T	38. John Bachmann	EPA-OAQPS-RTP		
T	39. Les Grant	EPA-NCEA/ORD-RTP		
T	40. Vanessa Vu	EPA-SAB		
T	41. Gerald Gleason	EPA-OGC		
T	42. Steve Silverman	EPA-OGC		
T	Others			

ATTACHMENT E

9. INTEGRATIVE SYNTHESIS

9.1 INTRODUCTION

9.2 SYNTHESIS OF AVAILABLE INFORMATION ON PM-RELATED HEALTH EFFECTS

9.2.1 Does the newly-available information continue to support consideration of fine and coarse particles as separate subclasses of PM pollution?

9.2.2 How does the newly-available information inform our judgments about the strength of the evidence for health effects related to ambient PM acting alone and in combination with other pollutants?

9.2.3 How does the newly-available evidence inform our understanding of the effects of fine and coarse particles and their major components?

9.2.4 How does the newly-available information inform our understanding of the subpopulations potentially susceptible to PM-related health effects?

9.2.5 What does the newly-available information imply with regard to potential public health impacts of human exposures to ambient PM in the U.S.?

9.3 SYNTHESIS OF AVAILABLE INFORMATION ON PM-RELATED WELFARE EFFECTS

9.3.1 What does the available information indicate about the direct and indirect effects on vegetation and natural ecosystem integrity of ambient PM and its major constituents?

9.3.2 What does the available information indicate about the effects on visibility associated with ambient PM and its major constituents?

9.3.3 What does the available information indicate about the effects on man-made materials associated with ambient PM and its major constituents?

9.3.4 What does the available information indicate about the relationships between atmospheric PM and climate change processes?

9. INTEGRATIVE SYNTHESIS

9.1 INTRODUCTION

- This chapter synthesizes information presented in Chapters 2 through 8 of this PM Air Quality Criteria Document (PM AQCD) by addressing several key questions that will inform the Agency's review of the primary and secondary PM NAAQS. As such, it is not intended as a stand-alone summary of the information presented in the earlier chapters, and it does not duplicate much of the key information contained in those chapters.

- In synthesizing the PM-related health and welfare effects information, this chapter will focus on integrating newly-available scientific information with the information available in the last review. In particular, in considering the PM-related health effects information, this chapter will build upon the integrative synthesis presented in the Chapter 13 of the 1996 PM AQCD.

- The goal of the chapter is to present updated syntheses of scientific information in a manner that will facilitate consideration of the key policy-related NAAQS issues to be addressed in the PM Staff Paper, prepared by staff in EPA's Office of Air Quality Planning and Standards. These policy-related issues include consideration of the appropriate indicators, averaging times, forms, and levels for PM standards in the U.S.. Consideration of these issues will be informed not only by the information contained in this chapter and throughout this criteria document, but also by additional policy assessments of scientific and technical information to be included in the PM Staff Paper.

- While this synthesis focuses on what has been learned from the new information that has become available since the last PM NAAQS review, it also highlights important uncertainties that remain and recognizes the value of continuing research in a number of key areas. Although the development of research recommendations in these areas is beyond the scope of this document, such recommendations are to be addressed in other PM research needs documents to be prepared by EPA and other organizations such as the NAS.

9.2 SYNTHESIS OF AVAILABLE INFORMATION ON PM-RELATED HEALTH EFFECTS

9.2.1 Does the newly-available information continue to support consideration of fine and coarse particles as separate subclasses of PM pollution?

9.2.1.1 Key Points from 1996 Integrative Synthesis

- The evidence indicates that "it would be appropriate to consider fine and coarse mode particles as separate subclasses" of PM pollution. This conclusion was based on differences between fine- and coarse-mode particles related to their chemical and physical

properties, evidence suggestive of different biological effects, and their derivation from different sources. (U.S. EPA, 1996, p. 13-91 through 13-94)

9.2.1.2 Integration of New Information

- Information on emission sources, formation mechanisms, atmospheric transformation, transport distances, composition, air quality patterns, and exposure relationships for fine and coarse mode particles

- Dosimetry studies on deposition and clearance patterns, including in particular comparisons between accumulation mode particles and coarse and ultrafine particles

- Toxicological studies on fine and coarse particles and their components

- Epidemiological studies, including the number of newly-available studies looking at fine and coarse particle effects

9.2.2 How does the newly-available information inform our judgments about the strength of the evidence for health effects related to ambient PM acting alone and in combination with other pollutants?

9.2.2.1 Key Points from 1996 Integrative Synthesis

- "The evidence for PM-related effects from epidemiologic studies is fairly strong, with most studies showing increases in mortality, hospital admissions, respiratory symptoms, and pulmonary function decrements associated with several PM indices. These epidemiologic findings cannot be wholly attributed to inappropriate or incorrect statistical methods, misspecification of concentration-effect models, biases in study design or implementation, measurement errors in health endpoint, pollution exposure, weather, or other variables, nor confounding of PM effects with effects of other factors. While the results of the epidemiology studies should be interpreted cautiously, they nonetheless provide ample reason to be concerned that there are detectable human health effects attributable to PM at levels below the current NAAQS." (U.S. EPA, 1996, p. 13-92)

- While epidemiological studies indicate increased health risks associated with exposure to PM, alone or in combination with other air pollutants, the role of PM as an independent causal factor has "not [been] completely resolved" based on the available studies using multiple air pollutants as predictors of health effects (U.S. EPA, 1996, p. 13-92).

9.2.2.2 Integration of New Information

- Consideration of the validity and coherence of evidence from studies world-wide

- Extensive new epidemiological evidence, including:

  - Information related to model selection/specification, with special focus on the reanalyses results and associated HEI review
  - Information on potential influences of co-pollutants, including multi-pollutant model results (e.g., NMMAPS), other approaches to evaluate co-pollutant confounding, and the results from single pollutant models in areas with different mixes of co-pollutants
  - Intervention studies
  - Consideration of the consistency and coherence of the epidemiological evidence

- Toxicological evidence related to evaluating the plausibility of PM effects and understanding potential mechanisms; including CAPs studies in particular

- Exposure-related information on PM and other gaseous pollutants (O_3, CO, etc.).

- Information related to biological plausibility of PM and the gaseous pollutants for respiratory- and cardiac-related effects

9.2.3 How does the newly-available evidence inform our understanding of the effects of fine and coarse particles and their major components?

9.2.3.1 Key Points from 1996 Integrative Synthesis

- The PM indices that have been "most consistently associated with health endpoints are fine particles (indexed by BS, COH, and $PM_{2.5}$), inhalable particles (PM_{10} or PM_{15}), and sulfate ($SO_4^{=}$)," whereas "[l]ess consistent relationships have been observed for TSP, strong acidity (H^+), and coarse PM ($PM_{10-2.5}$). . . . [and] none of these indices can completely be ruled out as a biologically relevant indicator of PM exposure."

- "The likelihood of ambient fine mode particles being significant contributors to PM-related mortality and morbidity among [the] elderly population is bolstered by: (1) the more uniform distribution of fine particles across urban areas . . . ; (2) the penetration of ambient particles to indoor environments . . . ; and (3) the longer residence time of ambient fine particles in indoor air, enhancing the probability of indoor exposure to ambient fine particles more so than for indoor exposure to ambient coarse particles."

- "Based on current evidence from epidemiologic, controlled human, human occupational, and laboratory animal studies, no conclusions can be reached regarding the specific chemical components of PM_{10} that may have the strongest biologic activity." Further, none of the various subclasses of PM [e.g., acid aerosols, bioaerosols, metals (including transition metals), and insoluble ultrafine particles] that have been considered "can be specifically implicated as the sole or even primary cause of specific morbidity and mortality effects." (U.S. EPA, 1996, p. 13-93)

9.2.3.2 Integration of New Evidence

- Focus on quantitative results from U.S. and Canadian epidemiological studies (with tables of study results, currently summarized in Tables 9-8, 9-10, and 9-11 in the June 2003 4th draft PM AQCD, to be moved to an Appendix)
  - Studies of $PM_{2.5}$ vs. $PM_{10-2.5}$ and fine and coarse components
  - Studies of PM_{10} in predominantly fine particle areas, as well as those in predominantly coarse particle areas
  - Factor analysis studies

- Toxicological evidence related to understanding potential mechanisms of fine and coarse particles and their major components

- Consistency and coherence of exposure, toxicological, and epidemiological evidence related to short-term (e.g., hours, days) and long-term exposures to fine particles, coarse particles, and their major components

9.2.4 How does the newly-available information inform our understanding of the subpopulations potentially susceptible to PM-related health effects?

9.2.4.1 Key Points from 1996 Integrative Synthesis

- "There is considerable agreement among different studies that the elderly are particularly susceptible to effects from both short-term and long-term exposures to PM, especially if they have underlying respiratory or cardiac disease. . . . Children, especially those with respiratory diseases, may also be susceptible to pulmonary function decrements associated with exposure to PM or acid aerosols." (U.S. EPA, 1996, p. 13-92)

9.2.4.2 Integration of New Information

- Information on pre-existing disease as risk factors (e.g., new evidence on diabetes)

- Information on age-related risk factors (e.g., new evidence on neonatal and infant effects)

9.2.5 What does the newly-available information imply with regard to potential public health impacts of human exposures to ambient PM in the U.S.?

9.2.5.1 Key Points from 1996 Integrative Synthesis

- "Efforts to quantify the number of deaths attributable to, and the years of life lost to, ambient PM exposure are currently subject to much uncertainty." (U.S. EPA, 1996, p. 13-87) Nonetheless, while "PM-related increases in individual health risks are small," they are "likely significant from an overall public health perspective because of the large

numbers of individuals in susceptible risk groups that are exposed to ambient PM." (U.S. EPA, 1996, p. 1-21)

9.2.5.2 Integration of New Information

- New studies on harvesting and life-shortening
- C-R functions and consideration of thresholds
- Studies on distributed lags and persistence of effects
- Comparative risks from short-term vs. long-term studies
- New evidence on children and infants
- New observed endpoints (e.g., doctor's visits), adding to pyramid of effects associated with exposure to ambient PM

9.3 SYNTHESIS OF AVAILABLE INFORMATION ON PM-RELATED WELFARE EFFECTS

- Since PM-related vegetation and ecosystem effects were not addressed in the 1996 PM AQCD, the discussion below will be drawn entirely from the information presented in Chapter 4, section 4.2 of the 2003 PM AQCD.
- Discussion of the other welfare effects below will reflect that there is generally only limited new information available in these areas relevant to an evaluation of effects related to ambient PM.

9.3.1 What does the available information indicate about the direct and indirect effects on vegetation and natural ecosystem integrity of ambient PM and its major constituents?

9.3.2 What does the available information indicate about the effects on visibility associated with ambient PM and its major constituents?

9.3.2.1 Key Points from 1996 PM AQCD

- "The relationships between air quality and visibility are well understood. Ambient fine particles are the major cause of visibility impairment. Significant evidence exists showing that reducing fine particle concentrations will improve visibility." However, visibility effects "are dependent upon not just the mass of pollutants, but on the size distribution and refractive index of particles, which are strongly influenced by relative humidity." (U.S. EPA, 1996, p. 1-18)

9.3.2.2 Integration of New Information

9.3.3 What does the available information indicate about the effects on man-made materials associated with ambient PM and its major constituents?

9.3.3.1 Key Points from 1996 PM AQCD

- "Particle exposure results in the soiling of painted surfaces and other building materials, increasing the cleaning frequency for exposed surfaces and possibly reducing their useful lifetimes." (U.S. EPA, 1996, p. 1-19) Damage to materials can result from the deposition of acid aerosols and the dissolution of acid forming gases on metal surfaces, increasing the corrosion of metals; "exposure to acid forming gases may also limit the life expectancy of paints and may damage various building stones and cement products beyond that resulting from natural weathering processes." (U.S. EPA, 1996, p. 1-20)

9.3.3.2 Integration of New Information

9.3.4 What does the available information indicate about the relationships between atmospheric PM and climate change processes?

9.3.4.1 Key Points from 1996 PM AQCD

- "Particles [primarily fine particles] suspended in the atmosphere affect the earth's energy budget and thus exert an impact on climate: (a) directly by increasing the reflection of solar radiation by cloud-free portions of the atmosphere, and (b) indirectly by affecting cloud microphysical properties in ways that increase the brightness and stability of clouds." Since aerosol lifetimes are much shorter than the time required for global mixing, "aerosol radiative effects are most likely to exert their influence on a regional rather than on a global basis." (U.S. EPA, 1996, p. 1-19, 1-21)

9.3.4.2 Integration of New Information

ATTACHMENT F

Roger O. McClellan, DVM, DABT, DABVT
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October 2, 2003

Dr. Phillip Hopke
Chair, Clean Air Scientific Advisory Committee
U.S. Environmental Protection Agency
Washington, DC

Dear Dr. Hopke:

This letter relates my views on the recently offered proposed approach to revision of Chapter 9, Integrative Synthesis of the Particulate Matter (PM) Criteria Document currently under development. Due to a scheduling conflict I will be unable to participate in the PM Panel Conference Call on October 3, 2003. I would appreciate having my comments entered into the record of the telephonic meeting in lieu of my voice participation.

The proposed outline is a step in the right direction. However, it still has serious deficiencies that will likely result in a final product that is not satisfactory. I have three major concerns with the proposed outline.

1) The outline fails to acknowledge in a clear format the purpose of the Criteria Document and, especially, the Integrative Summary. In my opinion, the Clean Air Act calls for an exposition of the scientific criteria that are critical to the setting of National Ambient Air Quality Standards for Particulate Matter. Namely, what are the scientific criteria for decisions on the (a) indicator(s), (b) averaging time, (c) numerical levels and (d) statistical form of prospective standards. The Clean Air Act does not call for an encyclopedia of what is known about PM and, in a synthesis chapter, a summary of what is known about PM.

2) In my opinion, the Clean Air Act calls for providing an exposition of the integrated scientific criteria based on current scientific knowledge. The present proposal

fails in this regard by using an approach of "this is what was related in 1996" and "this is what has been added." This serial approach will inevitably fall short of providing an integration of the available science. What is needed now is an integrative summary that is devoid of consideration of when the scientific information came to be known.

3) The proposed outline gives no indication that the resulting text will summarize critical scientific information that is needed for decisions on "how low is low enough?"; in short, the setting of a numerical level and statistical form for any PM indicator. In particular, this requires an Integrative Summary that clearly relates current knowledge, and attendant uncertainties, about the nature of ambient concentration-increased adverse health response relationships proceeding from the concentrations where the relationship is clearly evident and robust to levels where the relationship is highly uncertain and health responses are not distinguishable from background rates.

Let me expand on my expectations for this Chapter. As related in point 1 above, the Integrative Summary needs to clearly summarize what is known as regards potential indicators. As is well known, the choice of indicators is very limited because of a past policy of letting the collection of large scale monitoring data be driven by a "regulatory compliance approach to monitoring." Thus, epidemiological studies have primarily been conducted using TSP, PM_{10} and $PM_{2.5}$ as indicated for PM. Hence, it is realistic that the Integrative Summary note that, based on the science available today, three options are available; Total Suspended Particulates, PM_{10} and $PM_{2.5}$. It should further note that information on a fourth option, $PM_{10-2.5}$ is just beginning to emerge. It is also appropriate to note that the information available on any chemical specific PM indicator is very meager.

For each potential indicator the Integrative Summary should synthesize and integrate what is known as regards potential averaging times. Because of the nature of past research, the options are limited, 24 hours and annual. The Criteria Document (CD) needs to be explicit in indicating the relevant sciences that provides the scientific criteria for decisions on the use of a 24 hour and annual averaging time for each of the potential indicators. For example, it is possible that the science available today is sufficiently robust to allow consideration of both averaging times for some indicators while for other

indicators the science may only be sufficient to provide criteria for establishing one of the averaging times, 24 hours or annual, but not both averaging times.

The kind of Integrative Summary I am advocating clearly has a linkage to a decision analysis structure. The summary should present information in an organized manner that anticipates and facilitates the decisions that ultimately must be made on (a) indicators, (b) averaging times, (c) numerical levels, and (d) statistical forms. In advocating this approach I am not suggesting that the CD render decisions that are appropriately rendered in the Staff Paper.

I look forward to seeing the next version of the Integrative Summary of the CD. This next version provides an opportunity for the CD authors, and indeed the CASAC, to demonstrate the difference between an encyclopedia of knowledge of PM (the rest of the CD) and the scientific criteria essentially to setting the NAAQS for PM.

Sincerely,

Roger O. McClellan
Consultant
Particulate Matter Panel
Clean Air Scientific Advisory Committee

ATTACHMENT G

Comments on Integrative Synthesis (Chapter 9) Outline
by Morton Lippman

Dear All:

The Integrative Synthesis outline is very mich on target. I do have a few suggestions for changes. These are:

1) Section 9.1, first bullet, line 4: change "a stand-alone summary" to "an Executive Summary".

2) Sections 9.2.2 and 9.2.5, line 2: insert "fine and coarse thoracic" before "PM".

3) Section 9.2.3.2, fist bullet, last line: change "Factor analysis studies" to the more generic "Source apportionment studies".

4) Section 9.2.5.2: insert an additional bullet as the first in the list, i.e., "New studies of cardiac effects". This is at least as important as the bullets currently listed.

I also call your attention to two very interesting papers on the effects of coarse thoracic particles that fall within the extended citation period and were not cited in the 4th CD draft. These are:

Lin, M., Chen, Y., Burnett, R.T., Villeneuve, P.J., and Krewski, D. The influence of ambient coarse particles on asthma hospitalization in children: Case-crossover and time-series analysis. EHP 110:575-581(June 2002).

Zhang, J., Hu,W., Wei, F., Korn, L.R., and Chapman, R.S. Children's respiratory morbidity prevalence in relation to air pollution in four Chinese cities. EHP 110: 961-967 (Sept. 2002).

Mort
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ATTACHMENT H

Public Comment / Question
by Mr. Fred Lipfert

Fred - rather than take up time over the phone, I would be grateful if
you could transmit the following question and comment on my behalf. Thanks.

1. How does EPA plan to incorporate the results of the Veterans study inthe CD? Does EPA plan to synthesize results from all the long-term studies (including Hoek et al.), as in the time series studies?

2. The revised CD (or perhaps the staff paper) should take into account that the key epi studies from the 1980s used PM sampling methods substantially different from the FRM. Thus, the PM2.5 data used to set the NAAQS may differ systematically (including geographically) from the data that will be used for compliance with the NAAQS. This question should be at least addressed, if not answered. A bias as small as 1 ug/m3 could make animportant difference with respect to attainment.

Fred Lipfert
(631) 261-5735

ATTACHMENT I

Comments on EPA's Outline for Chapter 9 of the PM CD

by

George T. Wolff
(10/3/03)

At the end of the last PM review in 1996, there was widespread disagreement among the Panel members on the issue of causality, and the validity of some of EPA conclusions from the CD and Staff Paper (SP). As a result, EPA's conclusions from the 1996 CD and SP should not be taken as facts written in stone. Consequently, EPA's job in this new integrative summary is to integrate all the available information that supports or does not support each conclusion. It is inappropriate to present the 1996 conclusions as accepted doctrine. We have a number of Panel members who were not a part of the previous review, so it is important that they realize that some of these past conclusions were controversial.

For example, in 1996 meteorological confounders were dismissed based on the work of Kalkstein and the Hopkins group using the Philadelphia data. This work was used GAM and was not re-analyzed. In addition, the HEI reanalysis has put meteorology back on the table as a possible serious source of confounding. Furthermore, the HEI reanalysis of the GAM issue has also identified model specificity as an important factor in determining which pollutant is best associated with a given health outcome.

I also support Roger McClellan's comments that the foundation for the selection of the indicator, statistical form, averaging time, and level of the standard should be established in Chapter 9.

I also support Fred Lipfert's request that the Veterans study be given the same weight as the ACS study, and that a comparison of data from the IPN and FRM be done.